UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CITY OF CHARLESTON, WEST VIRGINIA, CITY OF HUNTINGTON, WEST VIRGINIA, CITY OF KENOVA, WEST VIRGINIA, and TOWN OF CEREDO, WEST VIRGINIA, municipal corporations, and other municipal corporations similarly situated,

Plaintiffs,

v.

Civil Action No. 2:17-4267

THE JOINT COMMISSION f/k/a THE JOINT COMMISSION ON ACCREDITATION OF HEALTH CARE ORGANIZATIONS, a not-for-profit organization, and its wholly-owned affiliate, JOINT COMMISSION RESOURCES, INC. d/b/a JOINT COMMISSION INTERNATIONAL, a not-for-profit organization,

Defendants.

COMPLAINT

Judge Joseph R. Goodwin of this Court has observed that there is "a clear, present, and deadly heroin and opioid crisis in this community. West Virginia is ground zero. […] The Southern District of West Virginia has been hit especially hard." *United States v. Walker*, No. 2:17-cr-10, 2017 WL 2766452, at *3, *7 (S.D. W. Va. June 26, 2017) (Memorandum Opinion and Order).

Because of this crisis, the City of Charleston, City of Huntington, City of Kenova, and Town of Ceredo, West Virginia ("Plaintiffs"), on behalf of themselves and all others similarly situated (the "Class" as defined below, "Municipalities" or "each Municipality"), by counsel Talcott Franklin P.C., The Webb Law Centre, PLLC, and Forbes Law Offices, PLLC, allege

against Defendants The Joint Commission f/k/a The Joint Commission on Accreditation of Health Care Organizations ("TJC" or "JCAHO") and its wholly-owned affiliate Joint Commission Resources, Inc. d/b/a Joint Commission International ("JCR", and, collectively with JCAHO, "Defendants") on information and belief:

I. SUMMARY

1. In 2001, Defendant JCAHO, as part of its certification program for health care organizations, teamed with Purdue Pharma L.P. and its affiliates ("Purdue"), as well as other opioid manufacturers, to issue Pain Management Standards (or "Standards") and other related documents that grossly misrepresented the addictive qualities of opioids and fostered dangerous pain control practices, the result of which was often the inappropriate provision of opioids with disastrous adverse consequences for individuals, families, and communities. These dangerous Standards, with minor modifications, exist to this day.

2. JCAHO zealously enforces these dangerous Standards through its certification program and has persisted in this course of action even after Purdue was found by the Food and Drug Administration to have misrepresented the quality of its opioid OxyContin in 2003, after Purdue pleaded guilty to felony criminal charges for making misrepresentations respecting OxyContin in 2007, and after warnings from health care professionals concerning the horrible impact wrought by the Standards.

3. Hospitals that routinely treat the residents of Plaintiffs were required to follow these Pain Management Standards to maintain JCAHO certification, which health care organizations deem essential to their continued operation. Defendant JCR supports JCAHO's certification program through consulting, publications, and training.

4. JCAHO retained and enforced the Standards in the face of a growing opioid epidemic and a chorus of criticism. In March 2016, the Centers for Disease Control and Prevention ("CDC") stated: "The science of opioids for chronic pain is clear: For the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits." The same CDC article noted: "Overall, 1 of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after the first opioid prescription; the proportion was as high as 1 in 32 among patients receiving doses of 200 MME or higher. We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

5. In July 2017, JCAHO agreed to change the Standards … effective January 1, 2018. Despite the President of the United States calling the opioid crisis a "national emergency" on August 11, 2017, the Acting Secretary of Health and Human Services determining that a "national health emergency exists nationwide" on October 26, 2017, and the fatal results of opioid therapy noted above, JCAHO exhibits no urgency in implementing the new Standards.

6. Even JCAHO's revised Standards fail to acknowledge a fundamental truth: **that some patients who do not fall into known risk categories (e.g., having current or former addictions or a family history of addiction) are highly vulnerable to opioid addiction, and medical science has no way of identifying these people until *after* they have started opioid treatment.** This recognition is particularly imperative for at least two reasons. First, experience has taught Municipalities, but apparently not Defendants, that the devastation wrought by addiction is traumatic in human and financial terms. Addiction rips apart families, causes overwhelming grief, demolishes productivity, imposes financial ruin, and imparts death and destruction not only on those who suffer directly from the disease, but also upon their families,

friends, employers, and communities. Second, due to their shorter lifespans and experiences, children are at the highest risk for this type of addiction. As any parent or Municipality that has watched a child descend into the disease of addiction can attest, this is a wrong of the most grievous nature. Defendants' misrepresentation and continued minimization of these risks warrant this Court's urgent attention.

7. JCAHO's revised Standards also fail to address the unique risks of opioid prescriptions to pregnant patients. In the United States, an estimated 14.4 percent of pregnant women are prescribed an opioid during their pregnancy. In Huntington, which also draws patients from Kenova and Ceredo, one in ten babies is born opioid dependent, about fifteen times the national average. One-fifth of babies born at Cabell Huntington Hospital were prenatally exposed to drugs, usually opioids. Babies exposed to opioids in the womb can suffer from neonatal abstinence syndrome ("NAS"). West Virginia has the highest rate of NAS in the nation, with 33 NAS births per 1,000 babies. The Thomas Memorial Hospital NICU is typically at or over capacity with NAS babies. NAS babies, their parents, and their communities suffer indescribable horror as these babies go through withdrawal from opioids. Babies suffering from withdrawal symptoms often release piercing painful haunting screams as they wring their hands and pull at their contorted faces. If fortunate enough to receive professional care, they are swaddled in blankets to protect their tiny bodies against waves of violent tremors. At times, their bodies become stiff as boards and they refuse food. These babies suffer severe cramps, muscle aches, diarrhea, fever, and abdomen pain. Some NAS babies are administered opioids. The long-term impact of NAS on these babies' development and lifespan is not yet known.

8. JCAHO's enforcement of its Pain Management Standards and its and JCR's widespread misinformation campaign about the safety of opioids has also led to an over-

prescribing of opioids, not only in terms of doses and necessity, but also in terms of quantity. Prescription opioids that go unused, combined with a lack of education about their dangers and the need to properly dispose of them, lead to tragic but predictable results: people looking to use drugs recreationally, very often teenagers, obtain these opioids and use them illicitly, resulting in addiction, overdoses, and death. Many parents discover too late that these supposedly safe prescription opioids fell into the hands of their children and their children's peers, who, with limited judgment and experience, had their lives derailed, if not destroyed, by opioid addiction. Roughly 70% people who took opioids for non-medical uses obtained them from a friend or relative.

9. Often in JCAHO's and JCR's own words, this Complaint sets forth Defendants' reckless and negligent indifference to the horrors of addiction, Defendants' profitable co-option by the opioid industry, and JCAHO's arrogant and intransigent refusal, despite an epidemic of human suffering, to modify or enforce its Pain Management Standards in a way that would reduce the risks of addiction.

II. PARTIES

10. Plaintiff City of Charleston is a municipal corporation located in Kanawha County, West Virginia. Charleston is a Class I city pursuant to W. Va. Code § 8-1-3(1), having a population of approximately 50,404 and adopting a charter in accordance with the laws of the State of West Virginia.

11. Plaintiff City of Huntington is a municipal corporation located in Cabell and Wayne Counties, West Virginia. Huntington is a Class II city pursuant to W. Va. Code § 8-1-3(2), having a population of approximately 49,138 and adopting a charter in accordance with the laws of the State of West Virginia.

12. Plaintiff City of Kenova is a municipal corporation located in Wayne County, West Virginia. Kenova is a Class III city pursuant to W. Va. Code § 8-1-3(3), having a population of approximately 3,400 and adopting a charter in accordance with the laws of the State of West Virginia.

13. Plaintiff Town of Ceredo is a municipal corporation located in Wayne County, West Virginia. Ceredo is a Class IV town pursuant to W. Va. Code § 8-1-3(4), having a population of approximately 1,450 and adopting a charter in accordance with the laws of the State of West Virginia.

14. Defendant JCAHO claims to be a not-for-profit organization founded in 1951, with offices in Oakbrook Terrace, Illinois and Washington D.C., that accredits and certifies nearly twenty-one thousand (21,000) health care organizations and programs in the United States. JCAHO certifies the health care organizations in the area where the Municipalities' residents receive health care, including CAMC General Hospital, CAMC Memorial Hospital, CAMC Women's and Children's Hospital, Highland Hospital, St. Francis Hospital, Thomas Memorial Hospital, St. Mary's Medical Center, Cabell Huntington Hospital, Mildred Mitchell-Bateman Hospital, and River Park Hospital. JCAHO has assets of roughly $190 million and receives over $150 million in revenue each year, largely from its certification programs. JCAHO's mission is to "continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value." JCAHO views the government and the public as "stakeholders." JCAHO's "vision" is that "[a]ll people always experience the safest, highest quality, best-value health care across all settings."

15. Defendant JCR claims to be a not-for-profit organization formed in 1998, with offices in Oakbrook, Illinois, that provides training, consulting, publications, and support for health care organizations seeking to comply with JCAHO's standards. JCR's "mission is to continuously improve the safety & quality of health care in the US and international community through the provision of education, publications, consultatation [sic] and evaluation services." JCR reported nearly $60,000,000 in total revenue in 2015.

16. Because of its certification program, JCAHO wields enormous power over health care organizations. Loss of certification is deemed by most health care organizations as disastrous to their continued operation. JCAHO certifies 99% of health care organizations in the United States.

III. JURISDICTION

17. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the Plaintiffs and Defendants are citizens of different states and the amount in controversy exceeds $75,000.

18. Venue in this Court is proper under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to this claim occurred in this judicial district, and JCAHO, as an accreditor of health care organizations in this judicial district, and JCR, as a consultant, publisher, and personal certification provider that administers examinations at a test center in this judicial district, can be found in this judicial district, which, according to this Court, "has been hit especially hard." *Walker*, No. 2:17-cr-10, 2017 WL 2766452, at *7.

IV. BACKGROUND

A. The Impact of Prescription Opioids.

19. JCAHO has been provided a sacred trust by government and the health care industry: the certification and accreditation of health care organizations. W. Va. Code § 16-5B-5a provides: "The state department of health and human resources shall grant an exemption from a periodic license inspection during the year following accreditation if a hospital applies by submitting evidence of its accreditation by the joint commission on accreditation of health care organizations or the American osteopathic association and submits a complete copy of the commission's accreditation report."

20. Opioids are a class of pain relieving medications that include the illicit drug heroin as well as the prescription medications oxycodone, hydrocodone, codeine, morphine and fentanyl. Opioid medications exert their analgesic effect by primarily binding to mu-opioid receptors in the brain. When opioids attach to these receptors, they reduce the perception of pain and produce a sense of euphoria, leading to positive reinforcement. An innate and hazardous property of opioids is their tendency, especially when used repeatedly over time, to induce tolerance. Tolerance occurs when the person no longer responds to the drug as strongly as they did at first, thus necessitating a higher dose to achieve the same effect. This tolerance contributes to the risk of addiction and overdose. Some opioids show tolerance after a single dose. In addition, drug dependence or susceptibility to withdrawal symptoms is another clinically important consequence of repeated exposure to escalating dosages of opioids. Why some people develop addiction to these inherently addictive medications while others do not is not clear.

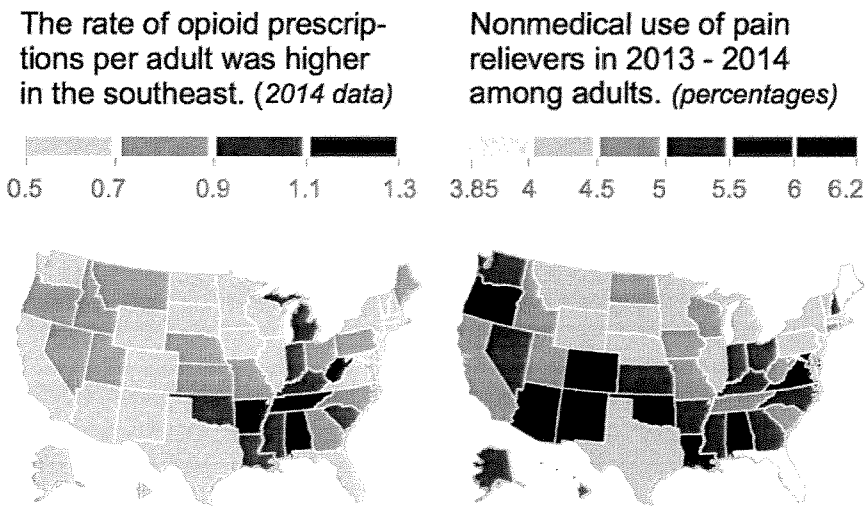
21. On August 11, 2017, the President called the opioid crisis a "national emergency," and in doing so said "it is a serious problem the likes of which we have never had."

The United States, with 4.6% of the world's population, consumes over 80% of the world's opioids. According to this Court:

> The heroin and opioid epidemic is one of the great public health problems of our time. The CDC found that opioids, primarily prescription pain relievers and heroin, are the chief drugs associated with overdose deaths. In 2015, the most recent year for which data is available, opioids were involved in 33,091 deaths, which is more than 63% of all drug overdose deaths. On average, ninety-one Americans die from an opioid overdose every day. Preliminary numbers for 2016 suggest that overdose deaths are growing at a rate comparable to the rate of H.I.V.-related deaths at the height of the H.I.V. epidemic.

Walker, 2017 WL 2766452, at *5 (citations omitted).

22. According to this Court, West Virginia "is a rural state deeply wounded by and suffering from a plague of heroin and opioid addiction." *Id.* at *3. As the following map demonstrates, West Virginia is among the states with the highest rate of opioid prescriptions per adult, but near the middle on the scale of non-medical use of pain relievers among adults.



23. Because of the flood of opioids, cities like Charleston, Huntington, and Kenova and towns like Ceredo have had to deal with the crippling effects of widespread opioid addiction. The CDC recently estimated that the total economic burden of prescription opioid abuse costs the United States $78.5 billion per year, which includes significantly increased costs for health care

and addiction treatment and dramatic strains on human services and criminal justice systems, as well as substantial losses in workforce productivity.

24. The cost in human lives and suffering is staggering. Opioids are the leading cause of accidental deaths in the country, surpassing deaths caused by car accidents. Opioid addiction destroys families, friendships, careers, and financial security. Exposure to these dangerous drugs comes through purportedly legitimate prescriptions written by doctors and dentists, making this epidemic unique.

25. Every day more than 1,000 people are admitted to emergency rooms across the country because of opioid-related abuse. Naloxone, a costly medication used to block and reverse the effects of an opioid overdose, is now routinely carried by law enforcement and EMTs if the Municipality can afford it or keep it in stock. Individuals addicted to opioids, but without a prescription or the resources to obtain them, often turn to heroin, sparking another crisis directly related to the widespread abuse of prescription opioids. As this Court has observed:

> These drugs are far more dangerous and far more available for abuse. Opioids are in the medicine cabinets of homes all over America and are available at every hospital and doctor's office. With the rise of prescription opioid abuse, heroin, which up until recently had been a tiny fraction of the illicit drug trade, came roaring back. The return of that pale horse may prove to be the event horizon of drug abuse and addiction.

Walker, 2017 WL 2766452, at *6. To that observation, this Court added in a footnote: "See Revelation 6:8 (King James) ('And I looked, and behold a pale horse: and his name that sat on him was Death, and Hell followed with him. And power was given unto them over the fourth part of the earth, to kill with sword, and with hunger, and with death, and with the beasts of the earth.')." *Id.* n.49. According to the National Institute on Drug Abuse, roughly 80% of heroin dependent users reported using prescription opioids prior to heroin. By contrast, in the 1960s, over 80% of heroin dependent users started with heroin. As one of the Plaintiffs' Fire Chiefs

recently noted, 80% of the heroin dependent people "that I deal with daily started with a legal prescription" to an opioid.

26. As this Court noted:

> West Virginia has the highest rate of fatal drug overdoses in the nation—and that rate continues to rise. This past year, 86% of overdose deaths involved at least one opioid. From 2001 to 2016, the number of people in the state who died from a drug overdose increased 400%. Our state's fatal drug overdose rate was 41.5 per 100,000 people in 2015, far above the national average of 16.3 per 100,000 people. The West Virginia Health Statistics Center released information that showed that at least 844 people in the state died of drug overdoses in 2016, an increase of 16.9% from 2015 to 2016.

Id. at *6 (citations omitted).

27. This Court noted earlier this month that it has:

> [P]reviously detailed the severe and devastating impact that the opioid crisis has had on this country and, particularly, on West Virginia. Since then, the statistics have grown only more frightening. From 2015 to 2016, the number of deaths caused by heroin overdoses increased by nearly 17%, and the number caused by fentanyl (and its analogues) more than doubled. Together, heroin, fentanyl, and prescription opioids currently account for nearly 78% of all drug-related deaths in 2016. The devastation caused by synthetic opioids will only increase as the drugs spread and additional analogues are created, gradually infecting and destroying the body politic.

United States v. Wilmore, No. 2:16-cr-00177, 2017 WL 4532156, at *4 (S.D. W.Va. Oct. 10, 2017) (Memorandum Opinion and Order) (citations omitted).

28. This Court further noted yet another devastating impact of this crisis on the community:

> As Mr. Wilmore's conduct makes clear, armed dealers are selling drugs in broad daylight at our local Walgreen's, at the Town Center Mall, and even in the parking lot of our children's middle schools. [...] Thus, when criminal activity is carried out in the context of a dangerous and devastating epidemic and involves conduct so dangerous to the Southern District of West Virginia, the public's interest in participation is at its zenith.

Id. at *5-6.

29. This Court further noted:

> The true victims here are the people of the Southern District of West Virginia. The current heroin and opioid epidemic is carving a path of pain and suffering that cuts across race, socioeconomic status, and age and afflicts everyone in our community.

Id. at *10.

30. The epidemic is not a coincidence. Instead, as set forth herein, it is in part the result of Pain Management Standards issued in 2001 and recklessly maintained and enforced to this day by Defendant JCAHO that led to a sharp increase in prescriptions for opioids.

31. Since issuing the Pain Management Standards, JCAHO has continued to prosper while Municipalities such as Charleston, Huntington, Kenova, and Ceredo have suffered significant economic damages, including, but not limited to, increased health care costs, insurance and self-insurance costs, health services costs, costs related to responding to and dealing with opioid-related crimes and emergencies, additional first responders, first responder and building department overtime, remediation of dilapidated and fire-damaged properties, criminal vagrancy, and other significant public safety costs and disruptions to quality of life and commerce, as described below.

B. JCAHO's Pain Management Standards.

1. JCAHO's 2001 Pain Management Standards.

32. On December 18, 2001, JCAHO issued its Pain Management Standards. JCAHO released with the Standards the Comprehensive Accreditation Manual for Hospitals: The Official Handbook.

33. The 2001 Standard RI.1.2.7 provides: "The health care organization addresses care at the end of life." The 2001 Standard RI.1.2.7 concludes that: "Effective pain management is appropriate for all patients, not just dying patients (see Standards RI.1.2.8 and P.E.1.4)."

34. The 2001 Official Handbook repeats this information for Standard RI.1.2.7.

35. The 2001 Standard RI.1.2.8 provides: "Patients have the right to appropriate assessment and management of pain." The 2001 Standard RI.1.2.8 requires: "The health care organization plans, supports, and coordinates activities and resources to assure the pain of all patients is recognized and addressed appropriately."

36. For the 2001 Standard RI.1.2.8, The Official Handbook provides "[e]xamples of Implementation of Standard RI.1.2.8," the first of which is: "Pain is considered the 'fifth' vital sign in the hospital's care of patients. Pain intensity ratings are recorded during the admission assessment along with temperature, pulse, respiration, and blood pressure."

37. The 2001 Standard P.E.1.4 provides: "Pain is assessed in all patients." The 2001 Standards provide "[e]xamples of Implementation for P.E.1.4," the first of which is: "All patients at admission are asked the following screening or general question about the presence of pain: Do you have pain now?"

38. The 2001 Official Handbook repeats this information for Standard P.E.1.4.

39. Under these 2001 Standards, pain management became appropriate for all patients, pain levels would be solicited and measured in all patients, and health care organizations would seek to elicit information about any pain the patient was suffering, in each case regardless of the patient's presentation.

40. Since this time, JCR actively published the Pain Management Standards, trained individuals in compliance with the Pain Management Standards through its Certified Joint Commission Professional ("CJCP") certification program, trained health care organizations in compliance with the Pain Management Standards through its consulting services, spread misinformation concerning the safety of opioids, and provided information on Pain Management Standards compliance strategies through its publications, trainings, and certifications.

2. JCAHO's Collaboration with Opioid Manufacturers.

41. Around the time JCAHO issued the Standards, The National Pharmaceutical Council, Inc. ("NPC") developed, "as part of a collaborative project with JCAHO," a monograph published in December 2001 titled "Pain: Current Understanding of Assessment, Management, and Treatments" ("2001 NPC Monograph"). The cover page of the 2001 NPC Monograph displayed both the NPC and JCAHO logos.

42. Members of NPC include several manufacturers and distributors of prescription opioids.

43. The 2001 NPC Monograph discussed "the high prevalence of pain, continuing evidence that pain is undertreated, and a growing awareness of the adverse consequences of inadequately managed pain." Indeed, the 2001 NPC Monograph pointed out that "[a]bout 9 in 10 Americans regularly suffer from pain, and pain is the most common reason individuals seek health care."

44. In short, the market for opioids was enormous, but largely untapped because health care providers feared turning patients into addicts.

45. As part of the collaboration with NPC, JCAHO produced its own monograph titled "Improving the Quality of Pain Management Through Measurement and Action" ("2001 JCAHO Monograph"). Both Monographs contained text stating: "The two monographs were produced under a collaborative project between NPC and JCAHO and are jointly distributed. The goal of the collaborative project is to improve the quality of pain management in health care organizations."

46. The 2001 JCAHO Monograph stated: "Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death. This attitude prevails despite

the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control."

47. Similarly, the 2001 NPC Monograph noted under "Common Misconceptions About Pain" "[t]he incorrect belief that: … [u]se of opioids in patients with pain will cause them to become addicted."

48. The scientific underpinnings for these definitive assertions were highly questionable. In defending the Pain Management Standards, David W. Baker, Executive Vice President at The Joint Commission, argues: "Many doctors were afraid to prescribe opioids despite a widely-cited article suggesting that addiction was rare when opioids were used for short-term pain." David W. Baker. *The Joint Commission's Pain Standards: Origins and Evolution* 2 (2017) ("Origins and Evolution"); *see also* David W. Baker. *History of The Joint Commission's Pain Standards: Lessons for Today's Prescription Opioid Epidemic.* 317(11) J. Am. Med. Ass'n 1117-1118 (2017) ("History"). In *Origins and Evolution*, Dr. Baker also notes that in "the Clarion Call for a Different Approach to Improve Assessment and Treatment of Pain," the President of the American Pain Society "emphasized the conventional wisdom of the day that 'therapeutic use of opiate analgesics rarely results in addiction,' although this was based on only a single publication that lacked detail about how the study was done." *Id.* at 2.

49. The "article" / "single publication" Dr. Baker referenced in *Origins and Evolution* was not even an "article," but a five-sentence letter to the editor of the New England Journal of Medicine, published January 10, 1980 ("NEJM Letter"). *See* Jane Porter & Herschel Jick, Addiction Rare in Patients Treated with Narcotics. 302(2) *N. Engl. J. Med.* 123 (1980).

50. In enacting and continually enforcing the Pain Management Standards, JCAHO made no effort until Dr. Baker's recently-published *Origins and Evolution* and *History* to investigate the quality or accuracy of the research reported in the NEJM Letter.

51. From 2000-2002, JCAHO sponsored a series of educational programs on its Pain Management Standards with various cosponsors, including pain-related groups such as the American Pain Society and the American Academy of Pain Medicine. These educational programs were devoted, in part, to correcting, in JCAHO's words, "[c]linicians' misconceptions about pain treatments" including "an exaggerated fear of addiction resulting from use of opioids."

3. JCAHO's Collaboration with Purdue.

52. JCAHO's Pain Management Standards provided opioid manufacturers with a golden opportunity to promote their products. Seizing on this opportunity with particular vigor was Purdue, the manufacturer of OxyContin.

53. During 2001 and 2002, Purdue funded a series of nine programs throughout the country to educate hospital physicians and staff on how to comply with JCAHO's Pain Management Standards for hospitals and that discussed postoperative pain treatment.

54. Purdue was one of two pharmaceutical companies to provide funding for JCAHO's pain management educational programs.

55. Under an agreement with JCAHO, Purdue was the only drug company allowed to distribute certain educational videos and a book about pain management; these materials were also available for purchase from JCAHO's website.

56. While JCAHO's Pain Management Standards never overtly required opioid treatments, the expectation that *every patient*, no matter how presented, should be asked about

pain vastly expanded the market for opioid treatments. Moreover, JCAHO's educational materials, trainings, and direct association with opioid manufacturers in general and Purdue specifically unconditionally signaled that the best way to meet the JCAHO's Pain Management Standards was to treat more and more patients with opioids. JCAHO also framed opioids as a patients' rights issue, even suggesting that health care providers who did not provide opioids were failing as physicians and perhaps risking liability for not making patients pain-free.

57. In January 2003, the U.S. Food and Drug Administration ("FDA") issued a warning letter to Purdue regarding two professional medical journal advertisements for OxyContin that minimized its risks and overstated its efficacy by failing to prominently present information from the boxed warning on the potentially fatal risks associated with OxyContin and its abuse and omitting important information about the limitations on the indicated use of OxyContin.

58. The FDA requested that Purdue cease disseminating these advertisements and any similar violative materials and provide a plan of corrective action. In response, Purdue issued a corrected advertisement, which called attention to the warning letter and the cited violations and directed the reader to the boxed warning and indication information for OxyContin.

59. Because of the corrected advertisement and JCAHO's close relationship with Purdue, JCAHO had reason to know that Purdue was minimizing OxyContin's risks and overstating its efficacy.

4. JCAHO's Continued Collaboration with Pharmaceutical Manufacturers.

60. In 2003, JCAHO developed "as part of a collaborative project with NPC," a monograph published in March 2003 titled "Improving the Quality of Pain Management Through Measurement and Action" ("2003 JHACO Monograph").

61. "[A]s part of a collaborative project with JCAHO," NPC developed a monograph published in March 2003 titled "Pain: Current Understanding of Assessment, Management, and Treatments" ("2003 NPC Monograph"). Both monographs had text stating: "The two monographs were produced under a collaborative project between NPC and JCAHO and are jointly distributed. The goal of the collaborative project is to improve the quality of pain management in health care organizations." The covers of both monographs displayed the logos of JCAHO and NPC.

62. The 2003 JCAHO Monograph stated:

a. "Clinicians' misconceptions about pain treatments could include an exaggerated fear of addiction resulting from use of opioids; confusion about the differences between addiction, physical dependence, and tolerance; or unwarranted concerns about the potential for the side effect of respiratory depression."

b. "In part, through increased visibility in the media, public opinion and attitudes toward pain relief have begun to change. Recent court cases concerning patients with unrelieved pain have heightened awareness of the need for appropriate pain management. Scrutiny of clinician practice includes not only the investigation of the overprescription of opioids but increasingly the study of cases of underprescribing."

c. "Many practices are faulty and outdated (e.g., promoting the idea that there is a high risk of addiction when opioids are taken for pain relief)."

63. The 2003 JCAHO Monograph reported under "Identifying the Problem" that its "team decided to evaluate the knowledge and attitudes of nurses. To assess staff knowledge, the team adopted the survey tool developed previously within the Baystate Health System, but made slight modifications to address home care issues. The survey was completed by approximately 80% of the nursing staff. Results pointed to opportunities for improvement related to conducting pain assessments, equianalgesic dosing, pain management in the elderly, and opioid side effects."

64. To help "solve" this problem, the 2003 JCAHO Monograph reported on "educational interventions."

65. As part of these educational interventions, "[a] laminated trifold pocket card was provided to all staff for quick reference to the World Health Organization analgesic ladder, opioid equianalgesic dosing, and opioid/coanalgesic equivalency tables."

66. The World Health Organization analgesic ladder provides that if pain occurs, there should be prompt oral administration of drugs in the following order: nonopioids (aspirin and paracetamol); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain.

67. In short, other than the initial oral administration of aspirin and paracetamol, the laminated trifold pocket card was devoted to the administration of opioids not just for pain relief, but with the goal of making the patient "free of pain."

68. JCAHO's endorsement and promotion of the "free of pain" goal contributed not only to the widespread prescription of opioids, but also to opioid doses strong enough to deliver freedom from pain.

5. Purdue's Guilty Plea to Felony Criminal Charges Related to OxyContin.

69. On May 9, 2007, in connection with a guilty plea to felony criminal charges for making misrepresentations respecting OxyContin, Purdue admitted: "Beginning on December 12, 1995 and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed or promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."

70. In the same document, Purdue also admitted: "From March 2000 through June 30, 2001, certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Liability Statement* and the amended statement

meant that OxyContin did not cause a 'buzz' or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to 'weed out' addicts and drug seekers."

6. JCAHO's 2009 Pain Management Standards.

71. In 2009, the Standards for hospitals and programs other than Behavioral Health Care said: "The hospital assesses and manages the patient's pain."

72. Nothing limits this Standard only to patients complaining of pain; indeed, the plain wording of this Standard requires assessing pain in *every* patient, no matter how presented.

73. Since 2009, the Behavioral Health Care Accreditation Standards have said: "The organization screens all patients for physical pain."

7. JCAHO and JCR Call Pain the Fifth "Vital Sign."

74. In November 2011, JCAHO and JCR published the following article in *The Source*, which provides "Joint Commission Compliance Strategies" and describes pain as "The Fifth 'Vital Sign'":


The Joint Commission
The Source
The Fifth "Vital Sign"
Complying with Pain Management Standard PC.01.02.07

8. JCR's Pharma-Funded Monograph.

75. In 2012, Janssen Pharmaceuticals, a division of Johnson & Johnson that manufactures opioids including Duragesic, a Fentanyl transdermal system, provided funding

support to the JCR publication of a monograph entitled *Pain Management: A Systems Approach to Improving Quality and Safety*.

76. The Monograph "describes the pain imperative" and provides a "toolkit" that "will guide you to assess and design your organization's pain management strategies."

77. Included in the "toolkit" is a document titled *Health Facts for You* under the imprimatur of the health system of University of Wisconsin Madison, which on the final page states "Used with permission of The Joint Commission."

78. *Health Facts for You*, subtitled "What You Should Know about Pain Management" appears designed for distribution to patients. Three of the questions and answers are:

> **What are the side effects of pain medicines?**
> It depends on the medicine. Side effects can include constipation, nausea, vomiting, itching, and sleepiness.
> [...]
> **Are you afraid that you'll become addicted to pain medicine?**
> This is a common concern of patients. Studies show that addiction is unlikely. This is especially true if the patient has never been addicted. Talk to your doctor or nurse about your fears.
> **Are you afraid that your pain medicine won't work if you take it for a long time?**
> This is called "tolerance." It means that after a while your body gets used to the medicine and you need to make a change to get pain relief. It's also possible that the condition causing your pain is getting worse or you have a new type of pain. You may need more medicine or a different kind of medicine to control your pain. Tell your doctor or nurse about your fears.

9. JCAHO's 2014 Clarification of the Pain Management Standards.

79. In November 2014, JCAHO issued a "Clarification to Standard PC.01.02.07." It stated:

> **Standard PC.01.02.07:** The [organization] assesses and manages the [patient's] pain.
>
> **Revised Rationale for PC.01.02.07 (New for Ambulatory Care and Office-Based Surgery Practice)**

> The identification and management of pain is an important component of [patient]-centered care. [Patients] can expect that their health care providers will involve them in their assessment and management of pain. Both pharmacologic and nonpharmacologic strategies have a role in the management of pain. The following examples are not exhaustive, but strategies may include the following:
>
> - Nonpharmacologic strategies: physical modalities (for example, acupuncture therapy, chiropractic therapy, osteopathic manipulative treatment, massage therapy, and physical therapy), relaxation therapy, and cognitive behavioral therapy
> - Pharmacologic strategies: nonopioid, opioid, and adjuvant analgesics

10. JCAHO's Continued Enforcement of the Pain Management Standards.

80. JCAHO's enforcement of the Pain Management Standards has also been reckless and negligent. To this day, despite the mountain of evidence demonstrating the dangers of opioids, JCAHO continues to emphasize the zealous and aggressive identification and management of pain and the prescribing of opioids as a solution. Indeed, the 2014 Clarification to Standard PC.01.02.07 states: "Both pharmacologic and nonpharmacologic strategies have a role in the management of pain" and *specifically lists* "opioids" as one of the "strategies."

C. The Pain Management Standards Cause the Over-Prescription of Opioids.

81. Recently, numerous experts and health care professionals have identified the Pain Management Standards as a significant contributor to the over-prescription of opioids.

82. An April 13, 2016, letter sent to the President and CEO of JCAHO by Physicians for Responsible Opioid Prescribing ("PROP"), and signed by numerous health care professionals stated:

> a. "The undersigned organizations and individuals are writing to request that the Joint Commission reexamine the Pain Management Standards (PC.01.02.07, PC.01.02.01 RI.01.01.01). Although we commend TJC for its recent clarification of PC.01.02.07, affirming that treatment strategies may include non-pharmacological approaches, we believe the Pain Management Standards continue to encourage unnecessary, unhelpful and unsafe pain treatments that interfere with primary disease management."

b. "Pain is a symptom, not a vital sign. Blood pressure, heart rate, respiratory rate and temperature are vital signs that can be objectively measured. Pain is only one of many distressing symptoms that patients can experience and to which health care professionals must be attentive. Pain is also not a single entity that warrants a formulaic 'titrate to effect' approach in response to a patient's reported pain score. Mandating routine pain assessments for all patients in all settings is unwarranted and can lead to overtreatment and overuse of opioid analgesics. Health care professionals are capable of using their clinical judgment to determine when to assess patients for pain."

c. "The United States experienced a sharp rise in prescriptions for opioid analgesics following the introduction of the Pain Management Standards. A recent study found that physicians prescribed opioids, often in high doses, in more than half of 1.14 million nonsurgical hospital admissions."

d. "According to the Centers for Disease Control and Prevention, sharp increases in opioid prescribing have led to parallel increases in opioid addiction and overdose deaths. Since the Pain Management Standards were introduced 15 years ago, more than 200,000 Americans have died from accidental overdoses involving prescription opioids."

e. "The Pain Management Standards foster dangerous pain control practices, the endpoint of which is often the inappropriate provision of opioids with disastrous adverse consequences for individuals, families and communities. To help stem the opioid addiction epidemic, we request that TJC reexamine these Standards immediately."

83. JCAHO responded to the PROP letter defensively and misleadingly.

84. JCAHO's response to the PROP letter included the following:

The Joint Commission does not endorse pain as a vital sign, and this is not part of our standards. Starting in 1990, pain experts started calling for pain to be "made visible." Some organizations implemented programs to try to achieve this by making pain a vital sign. The original 2001 Joint Commission standards did not state that pain needed to be treated like a vital sign. The only time that The Joint Commission standards referenced the fifth vital sign was when The Joint Commission provided examples of what some organizations were doing to assess patient pain. In 2002, The Joint Commission addressed the problems in the use of the 5th vital sign concept by describing the unintended consequences of this approach to pain management and described how organizations had subsequently modified their processes.

(Emphasis in original.)

85. On August 26, 2016, United States Surgeon General Vivek Murthy sent a letter to 2.3 million doctors asking for help in curbing the opioid crisis. Underscoring the magnitude of

the crisis, this letter represents the first time a United States Surgeon General has sent a letter directly to United States physicians. Among other things, the letter stated:

a. "I am asking for your help to solve an urgent health crisis facing America: the opioid epidemic. Everywhere I travel, I see communities devastated by opioid overdoses. I meet families too ashamed to seek treatment for addiction. And I will never forget my own patient whose opioid use disorder began with a course of morphine after a routine procedure."

b. "Nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

c. "The results have been devastating. Since 1999, opioid overdose deaths have quadrupled and opioid prescriptions have increased markedly – almost enough for every adult in America to have a bottle of pills. Yet the amount of pain reported by Americans has not changed. Now, nearly 2 million people in America have a prescription opioid use disorder, contributing to increased heroin use and the spread of HIV and hepatitis C."

D. JCAHO's 2017 Reexamination of the Pain Management Standards.

86. In 2016, JCAHO has reexamined the Pain Management Standards and in July 2017 issued new Standards *to take effect in January of 2018*, even though *a national health emergency exists* ***right now***. JCAHO's creation of Standards to take effect nearly half a year later in the face of a national epidemic is additional evidence of JCAHO's reckless and negligent failure to address the significant harm caused by its misinformation campaign, continued adherence to the Pain Management Standards in their various forms, and the continued enforcement of these Standards through JCAHO's certification programs. Tellingly, JCAHO admittedly only began "to develop standards related to safe and judicious prescribing of opioids" in 2016.

87. According to David W. Baker, Executive Vice President at The Joint Commission in *Origins and Evolution*:

In early 2016, The Joint Commission began a project to both revise its pain assessment and management standards and to develop standards related to safe and judicious prescribing of opioids. Three main areas were identified on this topic: 1) assessment and management of acute pain, 2) assessment and management of chronic pain, and 3) recognition, management, and/or referral of patients addicted to opioids. The Joint Commission decided to concentrate first on acute pain in the hospital setting.

After an initial literature review, The Joint Commission constituted a Technical Advisory Panel for potential conflicts of interest. All nominees were evaluated for potential conflicts of interest. In late 2016, new standards were drafted based on a literature review, input from the Technical Advisory Panel, and learning visits to organizations that had implemented innovative strategies to improve pain assessment and management. The draft standards were released in January 2017 and made available for public comments through February 2017. The draft standards recommend that pain assessment: include identification of psychosocial risk factors that may affect self-reporting of pain; involve patients to develop their treatment plan and set realistic expectations and measurable goals; focus reassessment on how pain impairs physical function (e.g., ability to turn over in bed after surgery); monitor opioid prescribing patterns; and promote access to nonpharmacologic pain treatment modalities. Changes to promote safe opioid use during and after hospitalization and to prevent diversion include: identify high risk patients; have equipment available to monitor high risk patients; facilitate clinician access to prescription drug monitoring program (PDMP) databases and encourage PDMP use prior to prescribing opioids; and educate patients and families regarding the safe use, storage, and disposal of opioids. Finally, The Joint Commission recommends that hospitals make efforts to identify patients addicted to opioids and to facilitate referral for treatment by informing clinicians about local addiction treatment programs.

E. JCAHO Failed to Prevent or Curtail the Opioid Crisis.

88. JCAHO could have prevented or curtailed the opioid crisis. JCAHO's certifications are viewed by health care organizations as critical to their continued operation. JCAHO and JCR had a duty to provide accurate information about opioids and enact and/or publish Standards that reduced the emphasis on identification of pain irrespective of patient presentation and instead emphasized:

a. opioid prescriptions as a last resort;

b. dissuading opioid prescriptions for pregnant patients;

c. setting realistic patient expectations about the management of pain;

d. honest discussions with chronic pain patients regarding the evidence respecting opioids in terms of the long-term treatment of chronic pain;

e. educating patients that some people who do not fall into known risk categories (e.g., having current or former addictions or a family history of the same) are highly prone to opioid addiction and medical science has no way of identifying these people until *after* they have started opioid treatment;

f. educating patients prior to opioid treatment as to the other risks of opioids, the safe use and keeping of opioids, and the prompt and proper disposal of unused prescribed opioids;

g. educating patients on the risks of differential tolerance;

h. telling younger patients (and their parents where appropriate) that determining whether a young patient falls into a known risk category for addiction is more difficult due to that patient's shorter lifespan and experience;

i. promoting alternatives to opioids in pain treatment;

j. identification of high risk patients and implementation of procedures designed to reduce those risks;

k. collection, analysis, and utilization of data related to opioid treatments; and

l. overall safety and minimizing risks associated with pain treatment.

V. DAMAGES

89. Because of JCAHO's conduct, the Municipalities have suffered significant and ongoing harm.

90. JCR operated in a supporting role to reinforce and magnify JCAHO's conduct through publicizing JCAHO's misinformation and reinforcing the Pain Management Standards through its consulting and publications. Thus, when JCAHO's conduct is referenced below, that phrase includes the supporting role JCR played in promoting, publicizing, publishing, consulting on, and training regarding the Pain Management Standards and in JCAHO's misinformation campaign on the safety of opioids.

91. JCR circulated publications and provided other information on the Pain Management Standards to health care organizations in West Virginia and this judicial district, including organizations that treat citizens of Plaintiffs. JCR also designated numerous

professionals in West Virginia as "Certified Joint Commission Professionals", offering testing for the designation in Dunbar, West Virginia. According to JCR, this designation "acknowledges your understanding of Joint Commission standards." Professionals with the CJCP designation often guide their health care organization's compliance with JCAHO standards, including the Pain Management Standards.

A. JCAHO's conduct has increased the Municipalities' health care costs.

92. JCAHO's conduct, resulting in a sharp increase in opioid prescriptions, has increased the Municipalities' health care costs. Each Municipality provides health insurance to its employees and their beneficiaries, meaning that when anyone covered by that Municipality's health insurance plan visits a doctor, fills a prescription, or otherwise incurs covered health-related costs, each Municipality pays a portion of those costs through its insurance premiums or self-insurance funds.

93. The health insurer or Municipality covering each Municipality's employees and their beneficiaries has been forced to spend significant amounts of money on prescription opioids, the bulk of which were prescribed for use in treating chronic pain pursuant to the Pain Management Standards.

94. In addition to prescription drugs, each Municipality, through increased insurance premiums or self-insurance funds, has paid significant amounts of money for doctors' visits, lab work, and other costs related to the prescription of opioid painkillers.

95. Further, when people covered by each Municipality's health plan become addicted to opioids, each Municipality incurs additional health care costs related to treating those opioid addictions.

96. Even for those people covered by a Municipality's insurance plan who do not become addicted, improperly prescribed opioids carry other costs for that Municipality. For example, when patients receive opioid prescriptions, they may forgo other steps to address the root causes of their chronic pain. Thus, even if patients can wean themselves off opioids, the underlying conditions may remain and become worse or more difficult and expensive to treat.

97. Nationwide, people who are prescribed opioid painkillers cost health insurers approximately $16,000 more than those who do not receive such prescriptions. Those increased costs, including costs borne by each Municipality, would have been avoided had JCAHO not spread misinformation and promulgated the Pain Management Standards that resulted in increased opioid prescriptions.

98. Each Municipality has also shouldered significant health-related costs outside of its health program because of Defendants' actions. For instance, when Municipal employees are prescribed opioid painkillers for chronic pain, they may be forced to miss work because the drugs' effects interfere with the ability to work. Because opioid prescriptions fail to treat the cause of the pain, the employees may continue to miss work due to the ongoing problems.

B. JCAHO's conduct has increased the Municipalities' workers' compensation insurance costs.

99. JCAHO's conduct, resulting in a sharp increase in opioid prescriptions, has increased each Municipality's workers' compensation insurance costs.

100. Each Municipality maintains workers' compensation insurance coverage, as required by West Virginia law, on its employees. Workers' compensation insurance provides compensation and health care benefits to a Municipality's employees injured on the job.

101. Through its self-insurance or payment of workers' compensation insurance premiums, each Municipality pays for doctors' visits, lab work, and other costs related to the prescription of opioid painkillers.

102. Each Municipality or Municipal workers' compensation insurer has spent significant money filling opioid prescriptions, many of which were unnecessary, as the injuries are typically back strains and other injuries that should be treated with physical therapy, lidocaine patches, and other non-opioid therapies. Thus, these drugs should not be subject to workers' compensation payments.

103. Not only are opioids inappropriate for treating the bulk of the workers' compensation claimants, but the use of opioids may produce addiction and slow the recovery process, meaning that the injured worker is off the job longer or never returns to work.

104. Had JCAHO not issued the Pain Management Standards and, with JCR, spread misinformation about opioids, the Municipalities would not have had to pay higher workers' compensation insurance costs for these drugs or for costs associated with delays in or failures of workers to return to work.

C. The Municipalities have incurred expenses providing human services to the community because of JCAHO's conduct.

105. Because many people who become addicted to opioids are originally exposed to these drugs through prescriptions, the opioid crisis has ensnared a broader cross-section of the population than previous drug epidemics. People who would not otherwise have encountered street drugs like heroin are initially hooked on prescription opioids. This has expanded the population of people who are addicted in the Municipalities. For these people, a prescription for opioids was the first step to addiction and drug abuse.

106. Because of this epidemic, numerous human services organizations in the Municipalities have opened or expanded to serve those with opioid addictions.

D. The Municipalities have incurred significant costs responding to opioid-related health emergencies.

107. Each Municipality has also borne enormous costs responding to opioid-related health emergencies. The Municipal Police Departments as well as the Municipal and Volunteer (but Municipality supported) Fire Departments provide emergency medical services in the Municipalities, responding to emergency calls, dispatching emergency medical service personnel, including emergency medical technicians, or EMTs, in ambulances or fire trucks.

108. Over the past decade, the number of opioid-related emergency calls to which the Municipal Police Departments and the Municipal and Volunteer Fire Departments have responded has risen sharply. Responding to opioid overdoses is expensive. It involves sending ambulances, engines, and specially-trained staff to the emergency. People who have overdosed on opioids must often be transported to the emergency room. Responding to such emergencies requires each Municipality to increase its police presence and incur significant overtime expenses. The costs of materials, maintenance, medication, and staff time, alone, are enormous and, of course, time, materials, and money spent addressing opioid overdoses means fewer resources and less time to respond to other medical emergencies.

109. Due in part to the increase in emergency calls, the costs to Plaintiffs with a Volunteer Fire Departments have greatly increased. The costs of operating a Fire Department have risen significantly, including daily calls to rescue overdose victims. One Plaintiff's Fire Chief notes that "26% of the time that my guys get a call … they're going to an overdose … 10% of that time, it's a death." That Municipality's Fire Department responds to 5.3 overdoses a day.

The Municipalities bear expenses for training and equipping first responders to remedy overdoses, naloxone kits, treating those that survive, and mortuary services for those who do not.

E. JCAHO's conduct has caused the Municipalities to incur significant additional public safety related costs.

110. JCAHO's conduct has also increased public safety costs for each Municipality.

111. Since promulgation of the Pain Management Standards and JCAHO's misinformation campaign, prescription opioids, including OxyContin, began showing up in drug arrests in each Municipality, and the presence of heroin on the streets of the Municipalities rose steeply.

112. The opioid epidemic has also increased public safety costs in other areas. The Municipalities bear significant costs related to an increased number of arrests for opioid-related crimes. This alone has placed a serious strain on the Municipalities' police resources. Some Municipalities have had to add additional police officers due to increases in opioid related societal consequences.

113. As this Court observed, legal opioid prescriptions begat illegal drugs. This encourages criminals from out of state to relocate to the Municipalities, either to deal drugs or to engage in criminal vagrancy and obtain drugs. This has created a vicious cycle requiring greater police presence while further taxing the Municipalities' resources, without the corresponding tax revenue that comes from traditional forms of city-to-city migration. This problem prompted the United States Drug Enforcement Agency to arrange for additional agents in Charleston to serve West Virginia, along with agents serving areas proximate to New Bedford, Massachusetts, Cincinnati, Cleveland, Raleigh, North Carolina, and Long Island, New York.

114. This astounding and devastating rise of opioids—both "legal" and illegal—has affected public safety in the Municipalities, and the Municipal Police Departments' and

Municipal and Volunteer Fire Departments' work and resources. Increased illegal drug trafficking has caused a rise in other criminal activities in the Municipalities. The price of prescription opioids on the black market is significant, forcing many addicts to turn to burglary or other property crimes to pay for their addiction. Not only does this impair the quality of life for everyone in each Municipality, but the Municipality is also forced to address these crimes, expending police and investigatory resources, which have direct costs to the Municipality. For example, some Municipalities were forced to buy software programs to monitor salvage yards and pawn shops for stolen merchandise, incurring ongoing expenses for such programs. Because each Municipality expends significant resources to address increased drug trafficking and property crimes, the Municipalities have had to divert resources from other public safety issues in the Municipalities.

115. Criminal vagrants from outside the state have harmed citizens of all socioeconomic status in the Municipalities. Among the most vulnerable are homeless West Virginians, who have been raped and assaulted by out-of-state criminal vagrants. One Plaintiff's Police Chief recently noted that he has seen things happen this year "that I've never seen in my career. I've seen a woman set on fire and murdered, I've seen a man get murdered with a machete. Our property crimes are through the roof. Most of the people watching probably know someone that's had their car broken into or garage broken into and this has been a particular bad summer for that." That Municipality recently saw a church that provided breakfast to the local homeless population suspend operation temporarily due to violence by out-of-state criminal vagrants.

116. In sum, JCAHO's conduct has unequivocally caused each Municipality serious and ongoing harm. Each Municipality's costs for health care, public safety, human and public

services, and law enforcement have all risen, and each Municipality as a community has suffered serious and tragic consequences as a result.

F. JCAHO's conduct has disrupted the Municipalities' quality of life and commerce.

117. JCAHO's conduct has also contributed to the deterioration of neighborhoods and increased the costs of remediating abandoned housing. People addicted to opioids often live in abandoned houses. The houses deteriorate rapidly due to damage, abuse, and neglect. Addiction can be so powerful that the addicted abandon standards of cleanliness and sanitation, producing dangerous environmental pollution, including used needles, human waste, and rotted food. The Municipalities bear the cost of removing the residents, repairing or bulldozing the houses, and remediating the environmental pollutants. At least one Plaintiff has requested funds from its urban renewal authority to remediate dilapidated housing related to the opioid crisis. Moreover, the crisis has caused the Municipalities to pay overtime for building department employees.

118. The pollution associated with the opioid crisis also takes place in public streets, parks, and parking lots, where the Municipalities bear the cost of cleaning up human waste, used needles, and trash discarded by people who have entered the Municipalities to obtain drugs.

119. West Virginia has some of the hardest workers in the world. Many work in difficult physical jobs that have a high risk of injury. Thus, many West Virginians suffer various injuries that, because of JCAHO's Standards and misinformation campaign, result in opioid prescriptions. The Municipalities and West Virginia businesses now have difficulty finding new employees who can pass a drug test or do not exhibit other symptoms of addiction, damaging the economy in the Municipalities and suppressing economic growth.

120. The deteriorating quality of life in the Municipalities, including deteriorating neighborhoods, criminal vagrancy, and overt drug dealing, has hampered the Municipalities'

efforts to attract new businesses and sources of tax revenue and employment. At least one Plaintiff had to impose a user fee on those working in the city but residing outside the city limits to pay for additional police officers.

121. Helping children affected by the opioid crisis further adds to the burden imposed on the Municipalities, including helping remediate the impact of birth addiction, youth addiction, or addicted parents. The impact of children growing up with one or more addicted parents will have tremendous social and financial consequences for the Municipalities, whether or not these children move into foster care. Children born addicted or who become addicted at a young age will require additional resources to remediate unique challenges as they grow older. The costs to the Municipalities will include special educational resources, on-going treatment and therapy, group homes, and remediating negative social outcomes.

G. Significant additional resources are needed to reduce the on-going harm wrought by JCAHO's conduct.

122. JCAHO's conduct has left each Municipality with a desperate need for treatment centers and educational resources to combat the growing addiction crisis.

123. Those suffering from addiction desperately require treatment, which in most cases is an on-going need. In many cases, treatment requires continued access to medication or facilities. Very often, those suffering from addiction lack the resources to pay for effective treatment.

124. Due to JCAHO's long and continuous misinformation campaign that misrepresented the safety of opioids, those not suffering from addiction require education to prevent them from becoming addicted. JCAHO's misinformation campaign was particularly insidious and harmful because the campaign resulted in trusted doctors misinforming their patients and their patients' parents about the safety of opioids. Correcting the misinformation

spread by JCAHO will require each Municipality to expend significant resources on developing and delivering effective educational campaigns and programs.

VI. CLASS ACTION

125. Plaintiffs bring this case on behalf of themselves and as a class action under Fed. R. Civ. P. 23(b)(2) and 23(b)(3) on behalf of all members of the following Nationwide Class: All cities and towns in the United States of America that contain or whose citizens are treated at a health care organization certified by JCAHO.

126. The Nationwide Class includes the following Statewide Subclass: All cities and towns in the State of West Virginia that contain or whose citizens are treated at a health care organization certified by JCAHO.

127. Plaintiffs reserve the right to amend the definition of the Classes if discovery or further investigation reveals that the class should be expanded or otherwise modified.

128. This action satisfies the requirements of Fed. R. Civ. P. 23(a)(1). Thousands of cities and towns nationwide and statewide have experienced damages caused by JCAHO's Pain Management Standards and continued enforcement thereof. Individual joinder of all Class Members is impracticable.

129. Each of the Classes is ascertainable because its members can be readily identified using public information. Plaintiffs anticipate providing appropriate notice to each certified Class, in compliance with Fed. R. Civ. P. 23(c)(1)(2)(A) and/or (B), to be approved by the Court after class certification or pursuant to court order under Fed. R. Civ. P. 23(d).

130. This action satisfies the requirements of Fed. R. Civ. P. 23(a)(2) and 23(b)(3) because questions of law and fact that have common answers that are the same for each of the

respective Classes predominate over questions affecting only individual Class Members. These include, without limitation, the following:

a. Defendants' conduct in promulgating, promoting, and/or enforcing the Pain Management Standards;

b. Whether JCAHO and/or JCR performed reasonable due diligence in promulgating, promoting, publicizing, and/or enforcing the Pain Management Standards;

c. Whether JCAHO's and/or JCR's promulgating, promoting, publicizing and/or enforcing the Pain Management Standards caused or contributed to an increase in opioid addiction;

d. Whether JCAHO's and/or JCR's promulgating, promoting, publicizing, and enforcing the Pain Management Standards was negligent, grossly negligent, or reckless;

e. Whether JCAHO's and/or JCR's acceptance of funds and assistance from pharmaceutical companies and/or their organizations constituted unjust enrichment; and

f. Whether JCAHO and/or JCR should be enjoined from further publication or enforcement of the Pain Management Standards.

131. This action satisfies the requirements of Fed. R. Civ. P. 23(a)(3) because Plaintiffs' claims are typical of the claims of the Class members and arise from the same course of conduct by Defendants. The relief Plaintiffs seek is typical of the relief sought for the absent Class members.

132. Plaintiffs will fairly and adequately represent and protect the interests of the Classes. Plaintiffs have retained counsel with substantial experience in prosecuting complex class actions.

133. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Classes, and have the financial resources to do so. Neither Plaintiffs nor their counsel have interests adverse to those of the Classes.

134. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(1) because the prosecution of separate actions by the individual Class members on the claims asserted herein

would create a risk of inconsistent or varying adjudications for individual Class members, which would establish incompatible standards of conduct for Defendants; and because adjudication with respect to individual Class members would, as a practical matter, be dispositive of the interests of other Class members, or impair substantially or impede their ability to protect their interests.

135. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(2) because Defendants have acted and refused to act on grounds generally applicable to each Class, thereby making appropriate final injunctive and/or corresponding declaratory relief with respect to each Class Member.

136. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(3) because a class action is superior to other available methods for the fair and efficient adjudication of this controversy. The common questions of law and fact regarding Defendants' conduct and responsibility predominate over any questions affecting only individual Class members.

137. No Class Member has initiated an action against JCAHO, despite numerous actions brought by Class Members against other defendants. Should those Class Members so amend their complaints to include JCAHO or bring additional actions against JCAHO, the burden imposed on the judicial system by such individual litigation would be enormous, making class adjudication the superior alternative under Fed. R. Civ. P. 23(b)(3)(A) and Fed. R. Civ. P. 23(b)(3)(B).

138. As noted previously, no judicial forum understands the opioid crisis better than the Southern District of West Virginia, making the concentration of claims in this judicial district ideal under Fed. R. Civ. P. 23(b)(3)(C).

139. The conduct of this action as a class action presents far fewer management difficulties, far better conserves judicial resources and the parties' resources, and far more effectively protects the rights of each Class member than would piecemeal litigation. Compared to the expense, burdens, inconsistencies, economic infeasibility, and inefficiencies of individualized litigation, the challenges of managing this action as a class action are substantially outweighed by the benefits to the legitimate interests of the parties, the court, and the public of class treatment in this court, making class adjudication superior to other alternatives, under Fed. R. Civ. P. 23(b)(3)(D).

140. Plaintiffs are not aware of any obstacles likely to be encountered in the management of this action that would preclude its maintenance as a class action. Fed. R. Civ. P. 23 provides the Court with authority and flexibility to maximize the efficiencies and benefits of the class mechanism and reduce management challenges. The Court may, on motion of Plaintiffs or on its own determination, certify nationwide, statewide and/or multistate classes for claims sharing common legal questions; utilize the provisions of Fed. R. Civ. P. 23(c)(4) to certify any particular claims, issues, or common questions of fact or law for class-wide adjudication; certify and adjudicate bellwether class claims; and utilize Fed. R. Civ. P. 23(c)(5) to divide any Class into subclasses.

141. The undersigned counsel for Plaintiffs and the Class request that this Court appoint them to serve as Class counsel; first on an interim basis and then on a permanent basis pursuant to Fed. R. Civ. P. 23(g). Undersigned counsel will fairly and adequately represent the interests of the Class, have identified or investigated the Class' potential claims, are experienced in handling class actions, other complex litigation, and claims of the type asserted in this action,

know the applicable law, will commit sufficient resources to represent the class, and are best able to represent the Class.

142. No alternative to this class action exists. If JCAHO's Standards persist, the Municipalities and their residents will continue to suffer unabated harm. For injunctive relief to be effective, the Pain Management Standards must change nationwide, and federal regulators have shown no interest in reforming JCAHO's Pain Management Standards.

COUNT I
NEGLIGENCE, GROSS NEGLIGENCE, RECKLESS AND WILLFUL CONDUCT

143. The elements of a negligence cause of action under West Virginia law are: (a) the existence of a duty; (b) the breach of that duty; (c) loss or damage to another caused by the breach; and (d) actual loss or damage to another. For a plaintiff to state a cause of action for negligence in Illinois, the complaint must allege facts sufficient to establish three elements: (1) the existence of a duty of care owed to the plaintiff by the defendant; (2) a breach of that duty; and (3) an injury proximately caused by that breach. Gross negligence and reckless and willful conduct under West Virginia law involve the same elements but different degrees of awareness or likelihood of loss or damage.

144. Defendants owed a duty of care to the Municipalities, including but not limited to taking steps to promulgate reasonable health care standards that would not lead directly to the misuse, abuse, and over-prescription of opioids. In violation of this duty, Defendant JCAHO promulgated, and Defendant JCR supported, Pain Management Standards that, in the words of numerous health care providers, led to over-prescription of opioids in the Municipalities by fostering "dangerous pain control practices, the endpoint of which is often the inappropriate provision of opioids with disastrous adverse consequences for individuals, families and

communities." Furthermore, Defendants engaged in a misinformation campaign that grossly misrepresented the safety of prescription opioids.

145. The paragraphs above are replete with allegations, many of them in Defendants' own words, that demonstrate Defendants' extreme recklessness in promulgating, enforcing, and/or providing information related to JCAHO's Pain Management Standards. As one example of many, consider JCAHO's and JCR's information to be provided to patients by health care professionals. Defendants respond to a question about the "side effects" of "pain medicines" with "It depends on the medicine. Side effects can include constipation, nausea, vomiting, itching, and sleepiness." Defendants make no mention of addiction or respiratory depression, which is a cause of death by overdose. When discussing patient fears concerning addiction, Defendants misleadingly and patronizingly respond: "This is a common concern of patients. Studies show that addiction is unlikely. This is especially true if the patient has never been addicted. Talk to your doctor or nurse about your fears." On the question of whether the pain medicine will stop working, Defendants again dangerously mislead, stating: "This is called 'tolerance.' It means that after a while your body gets used to the medicine and you need to make a change to get pain relief. It's also possible that the condition causing your pain is getting worse or you have a new type of pain. You may need more medicine or a different kind of medicine to control your pain. Tell your doctor or nurse about your fears." In fact, opioid patients exhibit "differential tolerance," i.e., the medication becomes less effective in relieving pain, but the patient develops little or no tolerance to the side effects like respiratory depression. Thus, the patient requires more and more medication to relieve pain, but lacks correspondingly enhanced resistance to respiratory depression, with often tragic results.

146. These Standards and misrepresentations violated Defendants' duty of care to each Municipality.

147. As a direct and proximate result of Defendants' negligence, gross negligence and willful and reckless, conduct, each Municipality has suffered and will continue to suffer harm and is entitled to damages in an amount that exceeds the sum or value of $75,000.

COUNT II
UNJUST ENRICHMENT

148. Plaintiffs incorporate by reference the allegations contained in this Complaint's preceding paragraphs.

149. Defendants accepted significant funding from Purdue and other pharmaceutical companies.

150. Defendants' acceptance of this funding co-opted Defendants so that JCAHO created and enforced, with JCR's support, Pain Management Standards that failed to recognize the dangerous and addictive nature of opioids.

151. These funds constitute blood money. Thousands have died and millions suffer because of Defendants' cooption.

152. The Class Members require these funds to remediate Defendants' failings.

COUNT III
DECLARATORY JUDGMENT

153. Plaintiffs incorporate by reference the allegations contained in this Complaint's preceding paragraphs.

154. Declaratory relief is intended to minimize "the danger of avoidable loss and unnecessary accrual of damages." 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2751 (3d ed. 1998).

155. An actual controversy exists between Defendants and Plaintiffs concerning the Pain Management Standards and their continued efficacy and enforcement.

156. Pursuant to 28 U.S.C. § 2201, this Court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

157. Because Defendants have refused to act, and in the face of ongoing and continuing harm, Plaintiffs seek a declaration that Defendant JCAHO may no longer:

a. Promulgate, utilize, or enforce Pain Management Standards in certifying health care organizations until such Standards: (i) discourage opioid treatment for patients except as a treatment of last resort; (ii) disclose that minors and the unborn are at greater risk for addiction due to their limited or non-existent medical history; and (iii) prominently include the following statement from the CDC, as updated from time to time: **"The science of opioids for chronic pain is clear: For the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits. … Overall, 1 of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after the first opioid prescription; the proportion was as high as 1 in 32 among patients receiving doses of 200 MME or higher. We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."**

b. Solicit or accept funding from a pharmaceutical company or organization of pharmaceutical companies related to the promulgation, explanation, or enforcement of any standards used to certify health care organizations;

c. Jointly produce with a pharmaceutical company or organization of pharmaceutical companies materials or programs related to any standards used to certify health care organizations; and

d. Distribute information produced by a pharmaceutical company or organization of pharmaceutical companies related to any standards used to certify health care organizations.

158. Plaintiffs also seek a declaration that Defendant JCR:

a. Must distribute corrective language to all health care organizations and individuals for which it has performed consulting, training, certifications, or assessments, or to who it has provided publications concerning the Pain Management Standards, which corrective language shall include the following statement from the CDC, as updated from time to time: **"The science of opioids for chronic pain is clear: For the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven**

and transient benefits. … Overall, 1 of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after the first opioid prescription; the proportion was as high as 1 in 32 among patients receiving doses of 200 MME or higher. We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

b. Distribute to health care organizations instructions that information contained in the *Health Facts for You* tool from the JCR Monograph *Pain Management: A Systems Approach to Improving Quality and Safety* and similar publications inaccurately disclosed the risks of pain medication and should not be distributed to patients or maintained by health care providers;

c. May no longer solicit or accept funding from a pharmaceutical company or organization of pharmaceutical companies related to the explanation, publication, consulting, or training concerning any standards used to certify health care organizations;

d. May not jointly produce with a pharmaceutical company or organization of pharmaceutical companies materials or programs related to any standards used to certify health care organizations; and

e. May not distribute information produced by a pharmaceutical company or organization of pharmaceutical companies related to any standards used to certify health care organizations.

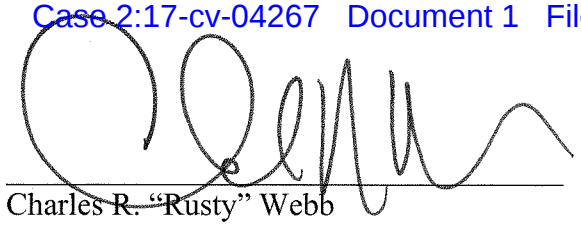
159. Plaintiffs seek the equitable relief of declaratory judgment, injunction, and remediation for the ongoing crisis of addiction Plaintiffs continue to endure.

WHEREFORE, the Municipalities respectfully request that the Court enter judgment against Defendants JCAHO and JCR and in favor of each Municipality and that it grant the requested equitable relief; each Municipality all damages permissible under law, including attorneys' fees and costs, and pre-judgment and post-judgment interest; and any further relief the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury on all claims and of all issues so triable.

Dated: November 2, 2017



Charles R. "Rusty" Webb
Bar No. 4782
The Webb Law Centre, PLLC
716 Lee St. E.
Charleston, West Virginia 25301
Phone: (304) 344-9322
Fax: (304) 344-1157
Email: rusty@rustywebb.com

W. Jesse Forbes, Esq.
Bar No. 9956
Forbes Law Offices, PLLC
1118 Kanawha Blvd., East
Charleston, West Virginia 25301
Phone: (304) 343-4050
Fax: (304) 343-7450
Email: wjforbes@forbeslawwv.com

Paul D. Ellis
Bar No. 8726
City Attorney
City of Charleston
P.O. Box 2749
Charleston, West Virginia 25330
Phone: (304) 348-8031
Fax: (304) 348-0770
Email: paul.ellis@cityofcharleston.org

Scott A. Damron
State Bar No. 935
City Attorney
City of Huntington
P.O. Box 1659
Huntington, WV 25717
Phone: (304) 696-4480
Fax: (304) 696-5538
Email: damrons@cityofhuntington.com

Talcott Franklin P.C. °
Dennis C. Taylor
Bar No. 6965
Debra Price
Bar No. 2979
831 Fourth Avenue, Suite 201
Huntington, West Virginia 25701
Phone: (304) 586-9847
Fax: (800) 727-0659
Email: dennis@talcottfranklin.com
Email: dee@talcottfranklin.com

Talcott J. Franklin *
Shannon W. Conway ò
Matthew Browne #
1920 McKinney Avenue, 7th Floor
Dallas, Texas 75201
Phone: (214) 321-3838
Fax: (800) 727-0659
Email: tal@talcottfranklin.com
Email: sconway@talcottfranklin.com
Email: matt@talcottfranklin.com

° A professional corporation.
* Licensed only in Michigan, North Carolina, South Carolina (inactive), and Texas. *Pro hac vice* motion to be filed.
ò Licensed only in D.C., Texas, and Virginia. *Pro hac vice* motion to be filed.
Licensed only in Texas. *Pro hac vice* motion to be filed.